REMARKS/ARGUMENTS

Amendments to the Specification

The disclosure has been objected to for the inclusion of the phrase "currently pending" on page 1, line 2. The offending phrase is now deleted.

In the Claims

Claims 1-31 remain in this application.

Claim Objections

The Examiner objects to claims 3-5, 8-10, 20, 25 and 30 for the following informalities:

In Claim 3, "the desired degree" lacks antecedent basis. Claims 8-10 are objected to as they fail to set forth any additional step(s) in the method. In Claims 20, 25 it is unclear as to what further structure is set forth. In Claim 30 the space between therapeutic and lumen should be deleted.

In response to these objections, claim 3 is now amended to read, "a desired degree" so as to eliminate the antecedent issue. (emphasis added)

Claims 20 and 25 are now amended to include the phrase "said working head is configured," thereby establishing that the structure of the working head is configured to operate as respectively set forth in each of the claims.

As requested, the oversized space between the words "therapeutic" and "lumen" has been corrected, however, since this did not require any amendment to the actual text of claim 30, Applicant continues to label it as (original) rather than (currently amended). If this labeling is erroneous, applicant request that the error be correct by way of an Examiner's Amendment.

§ 112 Rejections

The examiner has rejected claims16-31 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that

Claim 16 is incomplete as it fails to positively set forth the catheter the CPU or actuators as part of the claimed invention.

Claim 16 is now amended to positively claim a catheter, a CPU and one or more actuators as part of the claimed invention. (emphasis added)

§ 103 Rejections

The Examiner has rejected claims 1-13, 16-25, 28 and 30-31 under 35 U.S.C. 103(a) as being anticipated by McKenzie et al (US 5,993,469) and claims 1, 14, 26 and 27 are rejected as being unpatentable over McKenzie et al in view of US5,938,609 to Pomeranz as applied to claims 1 and 16, in further view of Masch (US 4,728,319). The Examiner's rejections are respectfully traversed.

Applicant is well aware of Pomeranz as it is mentioned as prior art in the instant application on page 5, line 15.

There is a substantial difference between the imaging guidewire described in the instant application and the imaging guidewire/catheter described in Pomeranz.

Firstly, from a structural point of view, the imaging catheter of Pomeranz contains a fixed a guidewire (18, 58, and 78 in Fig. 1, Fig. 2 and Fig. 3 respectively). This fixed guidewire extends freely distally to the catheter. The imaging elements (e.g., transducer-34) of the catheter are located proximally to the fixed guidewire.

Secondly, from a medical point of view, Pomeranz teaches in column 7, line 30-37,

> "...after the guidewire tip 18 enters the branch, the catheter 10 is moved forward so that the housing 16 is able to enter the stenosed region S. The guidewire tip 18 will than extend beyond the stenosed region.... The imaging system 30 within the housing 16 may than be used to image the stenosed region..." (emphasis added)

Applicant points our that Pomeranz also relates to a regular guidewire, which is designated as "movable guidewire", as is discribed in column 1, lines 61-67,

> "...The moveable guidewire is first positioned within the vascular system so that its distal end extends beyond the region of interest..." (emphasis added)

Therefore, Pomeranz clearly teaches that the guidewire, either fixed guidewire or movable guidewire, is forced to cross the lesion by itself prior to beginning any operational endeavor.

This is in contrast to the teachings of the instant application, which teaches that the imaging element, folding mirror 17 is located at the tip of the guidewire 16 adjacent to the cutter 6. Furthermore, as best illustrated in Figure 6 it is preferable that only the folding mirror 17 extends distally from the cutter 6. Other imaging parts such as the lens 18 reside inside the cutter 6. This construction is done in order to minimize the part of the imaging guidewire that freely extends in front of cutter 6. The imaging guidewire of the present invention is supported by the catheter and therefore the axial force that can be applied to the distal tip of the imaging guidewire is substantially higher than that of Pomeranz's fixed guidewire.

Further, according to the teachings of the instant application the imaging guidewire is not forced to cross the lesion by itself prior to beginning any operational endeavor, as taught on page 14, lines 7-9,

> "...ARIO's working head is not forced through the lesion prior to operation, but is rather slowly advanced by small increments while cutting the plaque..." (emphasis added)

Therefore it is designated as "non-crossing the lesion imaging guidewire", page 15, line 28,

> "...Incorporation of a non-crossing the lesion imaging guidewire..." (emphasis added)

Therefore, it is clearly taught by the instant application that the imaging guidewire is first used as a regular guidewire that is threaded up to the lesion without traversing the lesion. Then the catheter is advanced over the guidewire up to its distal

end. From this point on, the guidewire is used for imaging. The lesion is crossed by the combined catheter and guidewire as one unit.

This mode of operation makes the device of the present invention suitable for crossing Chronic Total Occlusions (CTO). CTO is a serious problem in angioplasty and occurs in about 30% of all angioplasty procedures. CTO is an occlusion that cannot be crossed by a standard guidewire. What happens is that the guidewire, during the insertion into the lesion, is bent and/or deflected and cannot cross the lesion. Sometimes there is a danger of artery perforation by the guidewire. Crossing the lesion is a mandatory requirement for many angioplasty procedures. Therefore, in cases when the guidewire cannot cross the lesion, the patient cannot be treated by angioplasty and is referred to other medical procedures, usually by-pass surgery.

Therefore, Applicant respectfully asserts that McKenzie et al. in view of Pomeranz clearly does not disclose either the method or the apparatus of the present invention. However, while continuing to traverse the Examiner's rejections, the Applicant, in order to expedite the prosecution of the instant application, has chosen to amend claims 1 and 16 so as to better distinguish the present invention over the cited prior art. Specifically, claim 1 is now amended to recite inserting a non-crossing the lesion imaging guidewire into the lumen of the blood vessel up to the intraluminal plaque without traversing the plaque. Likewise, claim 16 now recites a non-crossing the lesion imaging guidewire insertable in the lumen of the blood vessel up to the intraluminal plaque without traversing the plaque. Support for these amendments may be found of page 14, lines 7-9, on page 15, line 28 and in Figures 1, 5, 6 and 9.

Applicant further asserts that since Masch is cited as basis for rejecting claims that are depended from base claims that have now been shown to be allowable, such rejections are now moot.

The Applicant believes that the above comments completely overcome the Examiner's rejections of claims 1 and 16 on §103(a) grounds, and therefore the rejections of claims 2-15 and 17-31, which depend therefrom, are now rendered moot.

In view of the above remarks, it is respectfully submitted that the claims are in condition for allowance.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
DR. MARK FRIEDMAN, LTD
By _____
Mark M. Friedman
Attorney for Applicant
Registration No. 33,883